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Jeffry G. Weers

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EXAMINER

ARNOLD, ERNST V

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/616,448	Applicant(s) WEERS ET AL.	
	Examiner ERNST V. ARNOLD	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,12-15 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 12-15 and 21-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2, 6-11, and 16-20 have been cancelled. Claims 1, 3-5, 12-15 and 21-34 are pending and under examination. Applicant's amendments have necessitated a new ground of rejection. Accordingly, this Action is FINAL.

Withdrawn rejections:

Applicant's amendments and arguments filed 1/25/10 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-28 and 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 21 and 29 recite: "(FPF_{4+F})". This is not a simple acronym for "fine particle fraction". The parenthesis render the claim indefinite because it is unclear if the fine particle fraction is further limited by FPF_{4+F} or not. Claims 22-28 and 30-34 are rejected as being indefinite because they are dependent on an indefinite base claim. The claims will be interpreted as they read on a fine particle fraction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-5, 12-15 and 21-34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al. (US 5934273) and Eljamal et al. (WO 96/32096: reference BH on the IDS filed on 5/5/03) and Hanes et al. (US 5,855,913) and Radhakrishnan (US 5,049,389) as evidenced by Swarbrick et al. (Encyclopedia of Pharmaceutical Technology 1994, vol 9, pages 288-290).

Applicant claims a method for the pulmonary administration of a dry powder composition.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Andersson et al. teach methods of dispensing a dose of a pharmaceutically active compound comprising providing a dry powder inhaler containing a powder comprising the pharmaceutically active compound that is stored in the inhaler and consists of particles having a diameter of *less than about 10 microns*; administering the dose to the patient via inhalation through the inhaler with an emitted dose of *at least 40%* which means values greater than 40% including at least 60% or at least 80% are taught (Claim 1). The type of inhaler used is TURBUHALER (column 1, lines 17-19, 66; column 3, line 44; figure 1; and examples 1-5). The Examiner notes that Applicant also teaches TURBUHALER as the dry powder inhaler on page 21 Table 2, for example. There are no motor, rotating or vibrating parts to the TURBUHALER, which makes it a passive dry powder inhaler as evidenced by Swarbrick et al. who teach different dry powder inhalers such as the ROTAHALER and TURBUHALER and establish their equivalence (Figures 1 and Figure 2, pages 288-289). Furthermore, it is the Examiner's position that since it is the same dry powder inhaler as used by Applicant then it intrinsically has the same resistance as instantly claimed. The target peak inhalation flow rate for the TURBUHALER was 60 l/min (column 6, line 60). The geometric mean of budesonide deposited and absorbed in the lung was 32% with the range of 16%-**59% and 59%** is greater than the instantly claimed amounts of greater than 25%, 30%, and 50% (column 6, lines 35-37, for example). Andersson et al. teach that *any pharmaceutical active* compound, including antibiotics, can be formulated into a powder with *any powder characteristics* (column 4, lines 1-35). The pharmaceutically active compound can be contained in a pharmaceutical formulation containing common additives such as diluents and carrier substances (column 3, lines 48-67).

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Eljamal et al. teach compositions for dry powder inhalers and methods of treating conditions by oral inhalation with particles that have a mass median aerodynamic diameter of less than 5 microns (page 20, line 24; Page 35, Table 2; page 37, Table 3; and claims 1-33).

Eljamal et al. teach that particles of less than 5 micron size can be delivered to the deep lung for systemic circulation (page 20, lines 10-14).

Hanes et al. teach aerodynamically light particles incorporating a surfactant for drug delivery to the pulmonary system that has a tap density of less than about 0.4 g/cm^3 (Abstract; column 9, lines 1-55; and claims 1-33). Hanes et al. teach that the “mass mean diameter of the particles can be measured using a Coulter Multisizer II (Coulter Electronics, Luton, Beds, England). The aerodynamically light particles in one preferred embodiment are at least about 5 microns in diameter.” (column 7, lines 54-58). It is the Examiner’s position that “at least about 5 microns” includes values less than 5 microns as well as values at least 5 microns. Hanes et al. teach phospholipids as the surfactant in claims 14-17:

14. The composition of claim 1 wherein the surfactant is selected from the group consisting of a fatty acid, a phospholipid, and a poloxamer.

15. The composition of claim 1 wherein the surfactant is a phosphoglyceride.

16. The composition of claim 1 wherein the surfactant is dipalmitoyl L- α -phosphatidylcholine.

Hanes et al. teach any surfactant known in the art can work in column 5, lines 39-47:

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Surfactants known in the art can be used including any naturally occurring lung surfactant. Other exemplary surfactants include diphosphatidyl glycerol (DPPG); hexadecanol; fatty alcohols such as polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid, such as palmitic acid or oleic acid; sorbitan trioleate (Span 85); glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester such as sorbitan trioleate; tyloxapol and a phospholipid.

Hanes et al. teach porous microparticles (column 16, lines 25-35, for example).

Hanes et al. teach a wide variety of therapeutic agents including parathyroid hormone and leuprolide (column 10, lines 37-49 and claim 25).

Radhakrishnan teach inhalation method for treatment of lung diseases with tobramycin and other actives (claims 13, 15, 18 and 20).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Andersson et al. is that Andersson et al. do not expressly teach the mass median aerodynamic diameter of less than 5 microns and the bulk density of less than 0.5 g/cm³. This deficiency in Andersson et al. is cured by the teachings Eljamal et al. and Hanes et al.

2. The difference between the instant application and Andersson et al. is that Andersson et al. do not expressly teach a lipid matrix that comprises phospholipids or hollow porous microparticles. This deficiency in Andersson et al. is cured by the teachings of Hanes et al.

3. The difference between the instant application and Andersson et al. is that Andersson et al. do not expressly teach an active agent selected from the group consisting of tobramycin sulfate, leuprolide acetate, amphotericin B and parathyroid hormone. This deficiency in Andersson et al. is cured by the teachings of Hanes et al. and Radhakrishnan.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use mass median aerodynamic diameter of less than 5 microns and the bulk density of less than 0.5 g/cm^3 in the method of Andersson et al., as suggested by Eljamal et al. and Hanes et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) Andersson et al. suggest using any powder characteristics and: a) Eljamal et al. teach the beneficial property of obtaining deep lung delivery for systemic circulation with particles less than 5 micron in size; and b) Hanes et al. provide some guidelines on the diameter and density of the particles for one of ordinary skill in the art; and 2) the particles used by Andersson et al. must possess a diameter and density and the U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics such as diameter and density. Andersson et al. teach an unagglomerated particle size of less than about 10 microns in diameter (claim 1 (c)) which would read on particles of less than 5 microns. Andersson et al. simply did

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not calculate the mass median aerodynamic diameter or measure the bulk density. The burden is properly shifted to applicant to show otherwise.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use hollow porous phospholipid, such as dipalmitoylphosphatidylcholine, inert lipid matrix carriers in the method of Andersson et al., as suggested by Hanes et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: Andersson et al. suggests using common pharmaceutical formulation containing additives/carriers and Hanes et al. provide the nexus teaching to use phospholipids in dry powder inhalation pharmaceutical compositions. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Thus the disclosure of Hanes would render obvious the other species of instant claim 5 in the absence of evidence to the contrary. Hanes teaches that porosity affects the tap density which in turn regulates the aerodynamics and increasing porosity permits delivery of larger particle envelope volumes into the lungs (column 9, lines 2-12 and 19-25 and general discussions in this column), which is a desirable feature with inhaled medications.

With regard to the Anderson Cascade Impaction or multi-stage liquid impinger limitations, please note that the U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may

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present previously unmeasured characteristics such as diameter and density. The burden is properly shifted to applicant to show otherwise.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select actives from the group consisting of tobramycin sulfate, leuprolide acetate, amphotericin B and parathyroid hormone in the method of Andersson et al., as suggested by Hanes et al. and Radhakrishnan, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Andersson et al. teach using any pharmaceutical active. The selection of the sulfate salt of tobramycin is merely a matter of judicious selection by one of ordinary skill in the art.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments:

Applicant asserts that the combination of Anderson et al., Eljamai et al., Hanes et al. Radhakrishnan and Swarbrick et al. do not render independent claim 1, for example,

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unpatentable. Applicant asserts that Applicant's Example 2 shows only 15% lung deposition at a flow rate of 35 liters per minute using a Turbohaler. Thus, Applicant concludes, the Turbohaler administered composition does not provide a lung deposition of greater than 25% for flow rates from 10 to 60 liters per minute. Respectfully, the Examiner cannot agree. In contrast, the primary reference of Anderson et al. clearly teaches that the target peak inhalation flow rate for the TURBUHALER was 60 l/min (column 6, line 60). The geometric mean of budesonide deposited and absorbed in the lung was 32% with the range of 16%-**59% and 59%** is greater than the instantly claimed amounts of greater than 25%, 30%, and 50% (column 6, lines 35-37, for example). Respectfully, the primary reference appears to meet all those limitations and does not need further modification to meet the claim limitations. The principle of law states that: "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the answer depends on "whether the improvement is more than the predictable use of prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). Furthermore, the obviousness analysis "can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* At 418. In the instant case, it appears that it is merely predictable use of the prior art elements as there has not been any argument concerning unexpected results or synergy.

Applicant asserts that there is nothing in Anderson et al. to suggest a fine particle fraction of at least 60%. Please note that this is determined by an Anderson Cascade Impaction or multi-stage liquid impinger (see instant claim 21). Applicant asserts that one of ordinary skill in the art would expect the fine particle fraction to be significantly less than 60%. First of all this is an assertion without evidence. Second of all, as discussed above, the Examiner does not have this

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equipment to test the prior art compositions as instantly claimed. The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

Respectfully, Applicant's arguments are not persuasive and nothing unexpected or surprising has been shown. The rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 3-5, 11-15 and 21-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-7, 22 and

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36-38 of copending Application No. 10/141,219 (now revived) in view of Andersson et al. (US 5934273) Hanes et al. (US 5,855,913). The copending application teaches methods for administering a dry powder composition comprised of leupolide and phospholipid with a median diameter of between 0.5-4 microns, aerodynamic diameter of less than 5 microns, bulk density of about 0.5 g/cm³, dry powder inhaler, emitted dosages, and various phospholipids.

The copending application does not expressly disclose the resistance of the passive dry powder inhaler or hollow porous particles. This deficiency is cured by the teachings of Andersson et al. and Hanes et al., which are discussed in detail above and those discussions are hereby incorporated by reference, because the same passive dry powder inhaler is used by Andersson et al. as by Applicant and thus intrinsically has the same resistance. One of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application and Andersson et al. and Hanes et al. and would have had a reasonable expectation of success using the inhaler of Andersson et al.

2. Claims 1, 3-5, 11-15 and 21-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-25, 29 and 30 of copending Application No. 11/187,757 in view of Andersson et al. (US 5934273) Hanes et al. (US 5,855,913). The copending application is drawn to methods for treating a patient comprising administering particulates via inhalation having a mass median diameter of less than 20 microns, lipid matrix, amphotericin B, and a geometric diameter of less than 3 microns.

The copending application does not expressly disclose the resistance of the dry powder inhaler or hollow porous particles. This deficiency is cured by the teachings of Andersson et al. and Hanes et al., which are discussed in detail above and those discussions are hereby

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incorporated by reference, because the same passive dry powder inhaler is used by Andersson et al. as by Applicant and thus intrinsically has the same resistance. One of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application and Andersson et al. and Hanes et al. and would have had a reasonable expectation of success using the inhaler of Andersson et al.

This is a provisional obviousness-type double patenting rejection.

Claims 1, 3-5, 11-15 and 21-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-15, 17-19, 21-24, 26-34, 36-38, and 39-57 of U.S. Patent No. 7,306,787 in view of Andersson et al. (US 5934273). The patented claims are drawn to a method of delivering a therapeutic dose of a bioactive agent to the pulmonary air passages with a bulk density of less than 0.5 g/cm^3 , porous particles, diameter of 1-30 microns, emitted particles of at least 50% are delivered and an aerodynamic diameter of less than 5 microns. Phospholipids and actives as instantly claimed are taught.

The US Patent does not expressly disclose the resistance of the dry powder inhaler. This deficiency is cured by the teachings of Andersson et al. which are discussed in detail above and those discussions are hereby incorporated by reference, because the same passive dry powder inhaler is used by Andersson et al. as by Applicant and thus intrinsically has the same resistance. One of ordinary skill in the art would have recognized the obvious variation of the instant invention over the patented claims and Andersson et al. and would have had a reasonable expectation of success using the inhaler of Andersson et al.

Response to arguments:

Applicant will address the double patenting rejections upon the indication of allowable subject matter. Until that time the claims remain rejected.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/

Primary Examiner, Art Unit 1616